

OCT 3 1 1996



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

Philip L. Bateman  
P.O. Box 1105  
Decatur, IL 62525

In re Inventive Products , Inc.  
Request for Patent Term Extension  
U.S. Patent No. Re. 34,353

NOTICE OF  
DEFICIENCIES

The application for extension of the term of U.S. Patent No. Re. 34,353, which issued August 24, 1993, was received in the Patent and Trademark Office on February 20, 1996.

The application is informal because it fails to satisfy all of the requirements of 37 CFR 1.740(a). Under § 740(a), a formal application for the extension of patent term shall include, in part:

(10) A statement beginning on a new page, of the relevant dates and information pursuant to 35 U.S.C. 156(g) in order to enable the Secretary of Health and Human Services or the Secretary of Agriculture, as appropriate, to determine the applicable regulatory review period as follows: . . .

(v) For a patent claiming a medical device, the effective date of the investigational device exemption (IDE) and the IDE number, if applicable, or the date on which the applicant began the first clinical investigation involving the device if no IDE was submitted and any available substantiation of that date; the date on which the application for product approval or notice of completion of a product development protocol under section 515 of the Federal Food, Drug and Cosmetic Act was initially submitted and the number of the application or protocol; and the date on which the application was approved or the protocol declared to be completed.

(11) A brief description beginning on a new page of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to the approved product and the significant dates applicable to such activities; . . .

(17) An oath or declaration as set forth in paragraph (b) of this section.

As to item (10), the respective dates (effective date of the IDE or the date the first clinical investigation began if no IDE was submitted; the date on which the application for product approval or notice of completion of a product development protocol was initially submitted; and the date on which the product was approved or the protocol was declared to be completed) , the IDE number, if applicable, and number of the application for product approval under section 515 of the FFDCA need to be set forth.

As to item (11), on page 5 of the patent term extension application applicant describes certain "significant activities during the regulatory review period." However, the "significant activities" required by 37 CFR 1.740(a)(11) are the activities of the applicant for patent term extension or its agent before the Food and Drug Administration which lead to the approval of the product for commercial marketing and it is these activities which must be described. Note Exhibit E-1 of the application for patent term extension for U.S. Patent No. 4,587,258, copy enclosed.

As to item (17), the required oath or declaration has not been included. 37 CFR 1.740(b) states:

Any oath or declaration submitted in compliance with paragraph (a) of this section must be signed by the owner of record of the patent or its agent, specifically identify the papers and the patent for which an extension is sought and aver that the person signing the oath or declaration:

- (1) Is the owner, an official of a corporate owner authorized to obligate the corporation, or a patent attorney or agent authorized to practice before the Patent and Trademark Office and who has general authority from the owner to act on behalf of the owner in patent matters.
- (2) Has reviewed and understands the contents of the application being submitted pursuant to this section;
- (3) Believes the patent is subject to extension pursuant to § 1.710;
- (4) Believes an extension of the length claimed is justified under 35 U.S.C. 156 and the applicable regulations; and
- (5) Believes the patent for which the extension is being sought meets the conditions for extension of the term of a patent as set forth in § 1.720.

Accordingly, an oath or declaration in compliance with 37 CFR 1.740(b) is required.

The application for extension is informal because it fails to satisfy subsections (a)(10)(v), (a)(11), and (a) (17) set forth above. Applicant is given ONE MONTH from the date of this decision in which to file all the missing information noted above. Alternatively, as stated in 37 CFR 1.740 (c) applicant may seek to have this holding reviewed by filing a petition with the required fee, as

necessary, pursuant to 1.181, 1.182 or 1.183, as appropriate, within such time as may be set in the notice that the application has been held to be informal, or if no time is set, within one month of the date on which the application was held informal. The time periods set forth herein are subject to the provisions of 37 CFR 1.136.

Further correspondence with respect to this matter should be addressed as follows:

By mail:                   Assistant Commissioner for Patents  
                                 Box DAC  
                                 Washington, D.C. 20231

By FAX:                   (703) 308-6916  
                                 Attn: Special Program Law Office

By hand:                   One Crystal Park, Suite 520  
                                 2011 Crystal Drive  
                                 Arlington, VA

Telephone inquiries should be directed to Karin Tyson at (703) 306-3159.

H. Bernstein

Hiram H. Bernstein  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

Attachment- Application for patent term extension for U.S. Patent No. 4,587,256, including  
Exhibit E-1

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